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Datasheet for the decision of 13 March 2025

Case Number: T 1462/22 - 3.3.04

Application Number: 13195718.5

Publication Number: 2708559

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Language of the proceedings: EN

Title of invention:
Antigen-binding molecule capable of binding to two or more antigen molecules repeatedly

Patent Proprietor:
Chugai Seiyaku Kabushiki Kaisha

Opponents:
Glaxo Group Limited
Novo Nordisk A/S
James Poole Limited
Shire Human Genetic Therapies, Inc.
Ablynx N.V.
Alexion Pharmaceuticals, Inc.

Headword:
Antibody screening method/CHUGAI

Relevant legal provisions:

EPC Art. 76(1), 83, 84, 111(1), 123(2)
RPBA 2020 Art. 11, 13(2)

Keyword:

Amendments - added subject-matter (no)
Sufficiency of disclosure - (yes)
Claims - clarity (yes)
Remittal - special reasons for remittal (yes)

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 1462/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 13 March 2025

Appellant: (Patent Proprietor)	Chugai Seiyaku Kabushiki Kaisha 5-1, Ukima 5-chome Kita-ku Tokyo 115-8543 (JP)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Respondent: (Opponent 1)	GLAXO GROUP LIMITED 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Representative:	Hitchcock, Lucy Rose GSK Legal & Compliance - Global Patents 79 New Oxford Street London WC1A 1DG (GB)
Respondent: (Opponent 2)	Novo Nordisk A/S Novo Allé DK-2880 Bagsvaerd (DK)
Respondent: (Opponent 3)	James Poole Limited One Southampton Row London WC1B 5HA (GB)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent 4)	SHIRE HUMAN GENETIC THERAPIES, INC. 300 Shire Way Lexington, MA 02421 (US)

Respondent: (Opponent 5)	Ablynx N.V. Technologiepark 21 9052 Zwijnaarde (BE)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent 6)	Alexion Pharmaceuticals, Inc. 121 Seaport Boulevard Boston MA 02210 (US)
Representative:	J A Kemp LLP 80 Turnmill Street London EC1M 5QU (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 March 2022 revoking European patent No. 2708559 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	A. Chakravarty
	A. Bacchin

Summary of Facts and Submissions

I. The patent proprietor (appellant) filed an appeal against the opposition division's decision to revoke the European patent 2 708 559 (the patent).

II. The patent was granted on application EP 13 195 718.5, which was a divisional application of an earlier, parent application, published in English as EP 2 275 443, in accordance with Article 153(4) EPC (the parent application as filed or the parent application). The parent application had been filed under the PCT and published as WO 2009/125825 in the Japanese language.

III. The patent was opposed by six opponents (O1 to O6). The opposition proceedings were based on the grounds for opposition of lack of novelty and lack of inventive step (Article 100(a) in conjunction with Articles 54 and 56 EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

IV. Opponent 6 withdrew its opposition and is thus not a party to the present appeal proceedings. Thus opponents 1 to 5 are respondents I to V in the appeal proceedings.

V. In the decision under appeal, the opposition division dealt with objections against a main request, filed on 17 September 2020. These were under Rule 80 EPC, Article 83 EPC, Article 84 EPC, Article 76(1) EPC and Article 123(2) and (3) EPC). It also considered whether the subject-matter of the main request could validly claim priority under Article 87 EPC. The opposition division dismissed all objections other than those

under Article 83 EPC. The deficiencies under Article 83 EPC were held to apply equally to the invention claimed in auxiliary requests 1 to 7.

VI. The appellant submitted a statement of grounds of appeal to which only respondents II, IV and V replied. Respondents I and III made no substantive submissions in appeal proceedings. With its statement of grounds of appeal, the appellant submitted sets of claims of a main request and of an auxiliary request, both filed for the first time in the appeal proceedings.

VII. Claims 1 to 3 of the main request filed with the statement of grounds of appeal read:

"1. A method for producing a pharmaceutical composition comprising isolating an antibody by the screening method comprising the steps of:
(a) determining the antigen-binding activity of an antibody at pH 7.4;
(b) determining the antigen-binding activity of the antibody at pH 5.8; and
(c) selecting the antibody whose antigen-binding activity at pH 7.4 is 10 times or greater than that at pH 5.8;

and formulating the antibody selected in step (c) into a pharmaceutical composition, wherein the antigen is a soluble antigen, wherein said antibody includes an Fc region that binds to human FcRn, wherein the antigen-binding activity is assessed as dissociation constant KD.

2. A method for producing a pharmaceutical composition comprising isolating an antibody by the screening method comprising the steps of:

(a) binding an antibody to an antigen under a condition of pH 7.4;
(b) placing the antibody bound to the antigen of (a) under a condition of pH 5.8; and
(c) obtaining the antibody that dissociated under the condition of pH 5.8;

and formulating the antibody obtained in step (c) into a pharmaceutical composition, wherein said antibody includes an Fc region that binds to human FcRn.

3. A method for producing a pharmaceutical composition comprising isolating an antibody by the screening method comprising the steps of:
(a) binding an antibody to an antigen-immobilized column under a condition of pH 7.4;
(b) eluting the antibody that bound to the column under the condition of pH 7.4 from the column under a condition of pH 5.8; and
(c) collecting the eluted antibody; and formulating the antibody collected in step (c) into a pharmaceutical composition, wherein said antibody includes an Fc region that binds to human FcRn."

VIII. The board issued a summons to oral proceedings and subsequently, a communication pursuant to Article 15(1) RPBA, setting out its preliminary and non-binding opinion on some aspects of the appeal case.

IX. The appellant replied to the board's communication by letter dated 12 February 2025 and submitted a set of claims of a new main request. The previous main and auxiliary request were withdrawn.

X. Claim 1 (the sole claim) of the main request is identical to claim 3 of the former main request.

XI. Respondents I to V all informed the board that they would not attend the oral proceedings.

XII. Oral proceedings before the board were held as scheduled. At the end of these proceedings the chairwoman announced the decision of the board.

XIII. The appellant's submissions, relevant to the decision are summarised below.

Main request
Admittance (Article 13(2) RPBA)

There were exceptional circumstances which justified the admission of the main request. These were that the amendments made, which consisted of the deletion of claims 1 and 2 from the previous main request, significantly limited the claims and simplified the issues to be discussed overcoming the objections made by the opponents and which the board found persuasive according to its preliminary opinion.

Article 76(1) EPC/Article 123(2) EPC

Reference was made to the parent application in the published translation (EP 2 275 443). The application (EP 2 708 559 A2) contained the same disclosure.

The parent application expressly disclosed the production of a pharmaceutical composition using the antibody isolated by the disclosed screening methods.

The relevant disclosure was to be found in original claims 41 and 42 (dependent on claim 31). Here it was indicated that the antigen-binding molecule is used as a pharmaceutical composition. The description mirrored

this, for instance at page 24, paragraph [0165] which stated: "*Furthermore, the present invention also provides methods of screening for antigen-binding molecules which are particularly useful* ***when used as pharmaceutical compositions***." (emphasis by appellant)

The same disclosure was found at page 35, paragraph [0260]: "*The present invention also relates to pharmaceutical compositions that include antigen-binding molecules of the present invention,* ***antigen-binding molecules isolated by the screening methods of the present invention,...***" (emphasis by appellant).

Claim 1 of the new main request specified the first pH as 7.4 and the second pH as 5.8, which were disclosed as the most preferred, e.g. at paragraph [0183].

The antibody referred to in the claim included an Fc region that binds to human FcRn, which was also preferred according to the application. Paragraphs [0091] and [0095] disclosed that it was preferred that the antibodies, comprise an Fc region that binds to human FcRn.

The respondents argued that the parent application only disclosed methods of producing a pharmaceutical composition in claims 43 to 46, but that these claims required that the antibody be produced by the gene obtained in the earlier step. This was not correct because, as explained above, the parent application explicitly disclosed the subject-matter of claim 1 elsewhere.

XIV. There follows a summary of the respondents' submissions that were made in respect of claim 3 of the former main request, as far as relevant to the decision. This claim

is identical to the sole claim of the current main request. Submissions only relevant to claims 1 and 2 of the former main request are not relevant to the present decision and are not included. The respondents made no substantive reply to the Board's communication pursuant to Article 15(1) RPBA, nor did they reply to or comment on the appellant's letter dated 12 February 2025 or on the set of claims submitted with this letter. In particular, they made no comments concerning the admittance of this claim request under Article 13(2) EPC.

Amendments in respect of the parent application as filed (parent application) (Article 76(1) EPC)

Combination of screening method with the production of a pharmaceutical composition

The parent application did not disclose the methods as claimed which combined a method for producing a pharmaceutical composition with screening steps. Paragraph [0260] of the parent application provided a disclosure relating to pharmaceutical compositions of the invention. However, this paragraph gave no information relating to which particular screening methods should be used with a view to identifying antibodies to be incorporated into a production method.

The claimed method of producing a pharmaceutical composition included a step of formulating the pharmaceutical composition. However, the parent application did not provide any disclosure of such a method, and in particular, it did not disclose an active method of producing a pharmaceutical composition which included firstly conducting an isolating step, followed by a formulating step.

The parent application did disclose some methods for producing antigen-binding molecules, for example in the sections starting at paragraph [0200]. The methods described there however explicitly and in all instances referred to additional features and method steps such as the functional limitation - 'with improved pharmacokinetics', and the steps - 'obtaining the gene encoding the antigen-binding molecule selected in (c)' and - 'producing the antigen-binding molecule using the gene obtained in (d)'. There was no disclosure in the parent application that the antibody itself was to be isolated directly by the screening method. Instead, the gene encoding the antigen-binding molecule should be obtained and then the antigen binding molecule be produced using this gene. Thus, the parent application did not provide a direct and unambiguous disclosure of a method as claimed in which a screening method is conducted and an antibody isolated according to that screening method, and wherein the antibody so isolated is then formulated as a pharmaceutical composition.

The opposition division was furthermore mistaken to consider that the claimed method was disclosed in a combination of claims 28, 41 and 42, because these claims did not refer to a method for the production of a pharmaceutical composition. Furthermore, these claims did not comprise the features of isolating an antibody, and formulating it into a pharmaceutical composition.

Fc-region that binds to human FcRn

The feature "includes an Fc-region that binds to human FcRn", was not directly and unambiguously derivable from paragraphs [0091] and [0095] of the parent application, as alleged by the appellant. According to paragraph [0091], it was preferred that the antigen-

binding substance included an FcRn-binding region, for example, an antibody Fc region. Such an Fc region was disclosed as "preferred" (not as "more preferred" or "still more preferred"). Paragraph [0095] did not mention such Fc regions, but disclosed that preferably, the antigen-binding molecule "includes both antigen-binding activity (antigen-binding region) and FcRn-binding region" and that "In particular, preferred antigen binding molecule of the present invention includes a region that binds to human FcRn". The combination of an Fc region with a region that binds to human FcRn was not disclosed, let alone disclosed as preferred.

Dissociation constant, soluble antigen and pH

According to respondent II, the claim did not reflect that the antigen-binding activity needed to be assessed as dissociation constant, nor that the antigen needed to be a soluble antigen. It was furthermore not apparent where there was a basis for the specific pH values in the claim, particularly in the context of the methods of the claims. The difficulty in identifying such a basis was further exacerbated because the claims were now directed to methods for producing a pharmaceutical composition.

Clarity (Article 84 EPC)

Isolated/Isolating

The change of the term "isolated" in the patent as granted, to "isolating" in the present claim request, gave rise to unclarity. Firstly, it was unclear if this change introduced a new active step or not. Thus it was not clear if this feature could potentially delimit the

claim over the prior art. Secondly, the claim as granted was in the format of a product-by-process claim with the "isolated" supporting this format. The new wording made it impossible to know if the claim was a product-by-process claim defining an antibody or not.

Fc region that binds to human FcRn

This newly introduced feature was unclear because the person skilled in the art could not determine under which conditions the Fc region of the claim should be assayed for binding to human FcRn. It is well known that binding between two binding partners necessarily depends on several factors, *inter alia* pH and temperature. However, the claim (and the patent) were silent as to which tests or procedures would consistently enable the skilled person to verify whether or not an Fc region would bind to human FcRn and fall under the language of the claims. Even further, the claim did not indicate to which extent the Fc region should bind.

The requests of the parties

XV. The appellant (patent proprietor) requested that

- the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed with the letter dated 12 February 2025;
- document D90 not be admitted and that
- if the main request was found to comply with the requirements of Articles 76(1), 123(2) and (3), 84 and 83 EPC, then the case be remitted to the opposition division for further prosecution.

XVI. The respondents II, IV and V (opponents 2, 4 and 5) requested that the appeal be dismissed.

Respondent II further requested that
- no further auxiliary requests be admitted into the appeal proceedings and that
- if the Board decided to admit the claim requests and considered that the objections under Article 123(2) EPC, Article 83 EPC or Article 84 EPC did not apply to one or more of the requests as on file, then the issues of novelty and inventive step be considered by the Board and the case not be remitted to the opposition division for consideration of these issues.

Respondent V further requested
- not to admit all newly filed requests, and that
- if the Board was minded to set the decision under appeal aside then the case be remitted to the opposition division for further prosecution.

Reasons for the Decision

Oral proceedings in the absence of a party duly summoned (Rule 115(2) EPC)

1. Respondents I to V had all indicated that they would not attend the oral proceedings, which were held in their absence (Rule 115(2) EPC). They are treated as relying on their written case (Rule 15(3) RPBA).

Main request

Admittance (Article 13(2) RPBA)

2. The set of claims of the main request was filed with the appellant's letter dated 12 February 2025, in

reaction to the board's communication under Article 15(1) RPBA. It therefore represents an amendment to the appellant's appeal case, made after notification of a communication under Article 15 (1) RPBA and should, in principle, not be taken into account except in exceptional circumstances, justified with cogent reasons provided by the party concerned (Article 13(2) RPBA.

3. During the oral proceedings before the board, the appellant submitted that the exceptional circumstances which justified the admission of the main request were that the amendments made, which consisted of the deletion claims 1 and 2, from the previous main request significantly limited the claims and simplified the issues to be discussed overcoming the objections made by the opponents and which the board found persuasive according to its preliminary opinion. The amendments furthermore were not surprising for the opponents, who even decided not to attend the oral proceedings.

4. The board decided to admit the set of claims of the main request. Although respondent V had previously made a general request not to admit any newly filed requests, none of the respondents made any submissions in response to the appellant's filing of the main request.

5. An alleged simplification of a case, or even the mere deletion of claims cannot in general be said to constitute exceptional circumstances within the meaning of Article 13(2) RPBA, especially in cases where the objections the amendments are purported to overcome, have been on file for some time.

6. In the present case the circumstances are however different. In the proceedings before the opposition division, the appellant filed amended claims in reaction to the first and the second opposition division's communications, addressing objections which the opposition division found prejudicial to the patent.

7. Thus, the appellant submitted an amendment by deletion of claims in reaction to the board's preliminary opinion and none of the opponents reacted to this amendment. This situation may be regarded as exceptional circumstances. This holds true, even though the board did no more than agree with an objection that had already been on file, because the amendment by deletion overcomes objections that had not been a central topic of discussion in opposition. Such a factual situation should not lead to a disadvantage of a patent proprietor, who has efficiently addressed other more prominent objections in the course of proceedings, especially during the first instance proceedings. Furthermore, the present deletion of subject-matter does not bring about new issues to be discussed and successfully deals with the objections at stake, so that it truly entails a simplification of the procedure. The board is thus satisfied that in the present case, the simplification of the case brought about by the deletion of claims 1 and 2 of the former main request represents exceptional circumstances justifying the admission of the claim request.

Amendments (Article 76(1) EPC and Article 123(2) EPC)

8. The main request has a single claim. This claim represents an amended version of claim 3 of the main request considered by the opposition division

(submitted on 17 September 2020) to meet the requirements of Articles 123(2) and 76(1) EPC differing in that the pH in step (a) is specified as 7.4 and in step (b) is specified as 5.8. Finally it differs in that it specifies that the region that binds to human FcRn is an Fc region.

9. The claim finds a direct and unambiguous disclosure in the parent application as originally filed. The basis for the screening method steps (a) to (c) can be found in claim 31 and paragraph [0179] of the parent application, with the exception of the pH values and the specification that antibody "includes an Fc region that binds to human FcRn".

10. The pH value 7.4 in step (a) and the pH value 5.8 in step (b) find a basis in paragraph [0183] "*in a still more preferred combination, the first pH is pH 7.4 and the second pH is pH 5.8 or pH5.5*".

11. The specification that the antibody includes an Fc region that binds to FcRn is disclosed in paragraph [0091]: "[p]*referred FcRn-binding region includes, for example, antibody Fc regions*". Paragraph [0095] discloses that "*preferred antigen-binding molecule of the present invention includes a region that binds to human FcRn*". The board is of the view that the skilled person reading these passages consecutively and together would understand from the context that the preferred embodiment "antibody Fc regions" can bind the preferred embodiment human FcRn". Moreover, the choice of between human FcRn and non-human FcRn is a choice between two alternatives and does not require an undisclosed selection.

12. A method for producing a pharmaceutical composition comprising isolating an antibody by the above screening method is disclosed at least in paragraph [0260] of the parent application - "*The present invention also relates to pharmaceutical compositions that include antigen-binding molecules of the present invention, antigen-binding molecules isolated by the screening methods of the present invention...*".

13. Each of the above cited passages is also present in the application as filed, as follows:
Paragraphs [0091] and [0095] in the parent application are equivalent to paragraphs [0088] and [0091] in the application.
Paragraph [0179] in the parent application is equivalent to paragraph [0172] in the application.
Paragraph [0183] in the parent application is equivalent to paragraph [0176] in the application.
Paragraph [0260] in the parent application is equivalent to paragraph [0252] in the application.

14. Respondent II was of the view that the claim did not reflect that the antigen-binding activity had to be assessed as dissociation constant KD, nor that the antigen needs to be a soluble antigen. However, as set out above, the claimed subject-matter without these additional features finds a basis in the parent application. The features that antigen-binding activity had to be assessed as dissociation constant KD, and solubility of the antigen, represent alternative embodiments, disclosed in the parent application and reflected in claim 1 of the main request filed with the statement of grounds of appeal.

15. In view of the above considerations the claimed subject-matter meets the requirements of Article 76(1) EPC and Article 123(2) EPC.

Clarity (Article 84 EPC)

Isolated/Isolating

16. The respondents objected to the present wording "A method for producing a pharmaceutical composition comprising isolating an antibody by the screening method comprising the steps of" as unclear. In particular, the change of the term "isolated" to "isolating" was problematic because it was unclear if this step introduced a new active step or if this feature did not amount to an actual active step which could potentially delimit the claim over the art.

17. Secondly, the claim as granted was in the format of a product-by-process claim with the "isolated" supporting this format. The new wording made it impossible to know if the claim was a product-by-process claim defining an antibody or not.

18. The board is not convinced by the opponents' arguments. The claim is directed to a method for producing a pharmaceutical composition which comprises carrying out the screening steps (a) to (c) followed by formulating the identified antibody into a pharmaceutical composition. The skilled person would understand "isolating an antibody by the screening method comprising the steps of..." as meaning that the claimed method comprises the steps (a) to (c), by which an antibody is isolated. The claim is therefore a process claim and not a product-by-process claim.

Fc region that binds to human FcRn

19. This newly introduced feature was objected to as being unclear because the person skilled in the art could not determine under which conditions or to which extent the Fc region should bind the receptor.

20. In the board's view the skilled person would, in the light of their common general knowledge, have understood the expression "Fc region that binds to human FcRn" as referring to any ordinary Fc region which is capable of specifically binding to human FcRn. As such, the claim does not include antibodies without Fc regions or antibodies with Fc regions that cannot specifically bind human FcRn.

Disclosure of the invention (Article 83 EPC)

21. The opposition division held that the invention claimed in claim 1 of the main request before it, did not meet the requirements of Article 83 EPC because, in some situations, the selection criteria of step (c) would not only select the antibodies having the claimed pH dependency (i.e. having antigen-binding activity at pH 7.0 to pH 8.0 greater than that at pH 5.5 to pH 6.5) but also antibodies not having this functional property or would not allow the skilled person to determine if they are working inside or outside the scope of the patent. The opposition division gave several reasons for this. In relation to the screening method, the opposition division was of the view that because the precise screening method was not specified in the claim in relation to i) the pH value selected in the claimed range, ii) assay conditions (ionic strength) and iii) the choice of assay suit, it was an undue burden for

the skilled person to determine if an antibody falls inside or outside the scope of the claims.

22. A second set of reasons concerned iv) "*which dissociation constant [KD or kd] has to be chosen*", v) the evidence of non-working embodiments in the patent and vi) the type of Fc region of the antibody.

23. The opposition division in its decision did not make a separate assessment of whether or not the invention claimed in (former) claim 3 met the requirements of Article 83 EPC.

24. The amendments made in claim 1 (the single claim under consideration) render some of these objections moot by deletion of claims 1 and 2, to which they applied. The remaining claim does not relate to "(a) determining the antigen-binding activity of an antibody" but instead relates to a specific process comprising binding, elution and collection an antibody. Thus, objections concerning the skilled person's ability to determine antigen-binding activity do not apply to the claimed subject-matter. The board has seen no argument that would call into question the skilled person's ability to carry out the claimed method with regard to the performance of steps (a) to (c).

25. In the decision under appeal, the opposition division was persuaded that the claimed subject-matter was not sufficiently disclosed with respect to the feature "wherein the antibody includes a region that binds to FcRn" because "*..the patent fails to plausibly show that pH-dependent antigen-binding antibodies having a Fc binding portion that is not pH dependent, as encompassed in the claims, provide for improved antibody recycling*" (see point 9.3.1).

26. In the present claim antibodies isolated according to the screening method are defined as including an Fc region that binds to human FcRn. As set out under the heading of clarity (see point 20. above), the skilled person would have no trouble identifying what kind of Fc region the isolated antibody should have and no arguments have been put forward that the skilled person could not identify such antibodies.

27. The argument found convincing by the opposition division that the claimed antibody had to "*provide for improved antibody recycling*" is not persuasive for the claim at hand, and indeed it did not correctly apply to the claim considered by the opposition division. Improved antibody recycling is not an explicit feature of the claimed method nor can it be seen as necessarily implied that antibodies isolated by the screening method comprising the steps (a) to (c) need to exhibit it.

28. Thus, none of the objections of lack of sufficient disclosure are convincing and the claimed invention meets the requirements of Article 83 EPC.

29. In summary of the above considerations, the board was not convinced by any of the objections made by the respondents under Article 76(1) EPC, Article 123(2) EPC, Article 83 EPC or Article 84 EPC.

Remittal (Article 111(1) EPC and Article 11 RPBA)

30. Pursuant to Article 111(1), second sentence, EPC the board of appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution. Under Article 11

RPBA, the board shall not remit a case for further prosecution, unless special reasons present themselves for doing so. In this case, the board has reviewed the decision under appeal and has found that the main request and its subject-matter satisfies the requirements of Article 76(1) EPC/Article 123(2) EPC, Article 84 EPC and Article 83 EPC. The decision under appeal did not deal with the further requirements of the EPC, in particular those in Article 54 EPC and Article 56 EPC. In the present case, this circumstance is considered to fall within the meaning of "special reasons" referred to in Article 11 RPBA and is in line with Article 12(2) RPBA which confirms that primary object of the appeal proceedings is to review the decision under appeal in a judicial manner.

31. In accordance with the requests of the appellant and of respondent V, the board decided to remit the case to the opposition division for further prosecution on the basis of claim 1 of the main request submitted with letter of 12 February 2025.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution on the basis of claim 1 of the main request submitted with letter of 12 February 2025.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated